

**REMARKS**

This Response, filed in reply to the Office Action dated June 4, 2009, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1, 5, 6, 16, 20 and 21 are currently under examination, and are rejected. No new matter is added by way of this Response. Consideration of the remarks herein is respectfully requested.

**Information Disclosure Statement**

Applicants thank the Examiner for returning a signed and initialed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed May 19, 2009, indicating consideration of the references therein.

**Withdrawn Rejections**

Applicants thank the Examiner for withdrawal of the rejection of Claim 16 under 35 U.S.C. § 102(b).

**Claims 1, 5, 6, 16, 20 and 21 Are Patentable Under 35 U.S.C. § 103(a)**

1. On page 2 of the Office Action, Claims 1, 5, 6, 16, 20 and 21 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Brantman (U.S. Patent No. 4,687,782), of record.

In making the rejection, the Office relies upon Brantman as allegedly disclosing a composition *consisting essentially of* carnitine, isoleucine, leucine, valine, glutamine, and a whey

protein, adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise.

The Office acknowledges the criticality of carnitine in protecting against the toxic effects of ammonia produced by catabolism of the branched amino acids in the composition of Brantman.<sup>1</sup> However, the Office contends that, despite Brantman's disclosure of the criticality of carnitine in protecting against ammonia toxicity, and Brantman's disclosure of the desirability of rapid removal of ammonia from muscle, one of ordinary skill in the art would readily have omitted carnitine from the composition of Brantman because "carnitine is an amino acid that is synthesized in the body ... and its quantity in [the] composition [of Brantman] does not appear to be of a significant quantity."

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

In sustaining the rejection, the Office purports that one of ordinary skill in the art would readily omit an element from a supplement for enhancing protein synthesis in skeletal muscle, *if* that element can be endogenously produced by the body. Applicants disagree. Applicants note that the stated purpose of the composition of Brantman is to provide "a dietary supplement which provides the best metabolic milieu to permit and encourage protein synthesis in skeletal muscle and in liver ... [and] to supply an amino acid supplement which is directed at optimizing protein synthesis in skeletal muscle and liver ... so as to achieve a diet which is enriched with specific amino acids (carnitine, glutamine, isoleucine, leucine and valine) ..." (Emphasis added.) See column 4, lines 17-30. That is, Brantman aims to provide a supplement to **maximize** protein

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<sup>1</sup> See the paragraph bridging pages 4 and 5 of the outstanding Office Action.

synthesis in skeletal muscle. Thus, because Brantman adds exogenous carnitine to provide the best metabolic milieu for *maximizing* protein synthesis, one of ordinary skill in the art would not readily have omitted carnitine from the composition of Brantman simply because it can be produced endogenously; such reasoning is irreconcilable with the very purpose of the composition of Brantman, *i.e.*, as a supplement to provide enriched levels of particular amino acids over that which are normally present in the body, in order to promote muscle adaptation to strenuous exercise by sparing branched amino acids in muscle from catabolism, by stimulating protein synthesis and neoglucogenesis, by maximizing metabolism of pyruvate to alanine, and by encouraging protein efflux from muscle. See column 3, lines 18-37. One of ordinary skill in the art would immediately recognize that carnitine is included in the composition of Brantman to increase the normally-occurring level of carnitine in the body, in order to maximize fatty acid oxidation and ammonia detoxification; for this reason, one of ordinary skill in the art would not simply have dispensed with carnitine, thereby reducing the potential free carnitine in the body available to participate in fatty acid oxidation and ammonia detoxification, when Brantman discloses the *criticality* of carnitine for these processes, and the importance of these processes in maximizing protein synthesis in skeletal muscle.

Indeed, Applicants respectfully submit that the premise on which the rejection is based, *i.e.*, that one of ordinary skill in the art would readily omit an element from a supplement for enhancing protein synthesis in skeletal muscle, *if* that element can be endogenously produced by the body, erroneously fails to consider whether the amount produced by the body is optimal for muscle growth, and allows for maximal protein synthesis; the art recognizes a plethora of exogenous supplements, *that although produced endogenously*, can significantly enhance muscle growth when added in greater amounts exogenously (*e.g.* creatine). While the Office arbitrarily

asserts that one of ordinary skill in the art would have chosen to omit carnitine alone (even although glutamine is also produced endogenously), the Office has failed to provide any evidence demonstrating that, at the time of the invention, one of ordinary skill in the art would have recognized the amount of endogenously-produced carnitine to be optimal, and sufficient, for maximal protein synthesis in skeletal muscle and liver (the purpose of the Brantman composition), such that they would have recognized that omitting carnitine from the composition of Brantman would not detract from its ability to *maximize* protein synthesis and muscle adaptation to strenuous exercise. To the contrary, as evidenced by the partial English-language translation of JP2003-135033, attached herewith<sup>2</sup>, the state of the art at the time of the invention was such that those of ordinary skill in the art did not recognize that the amount of endogenously-produced carnitine was optimal, and sufficient, for maximal protein synthesis in skeletal muscle.

Moreover, Applicants strongly, but respectfully, disagree that one of ordinary skill in the art would recognize carnitine as being dispensable merely because it is present in lower amounts than the other amino acids therein. As would be appreciated by one of ordinary skill in the art, carnitine is present in lower amounts due to the differing biological roles of carnitine vis-à-vis the other amino acids therein (*i.e.*, carnitine is not incorporated into muscle mass, nor is it catabolized for energy), and also due to the lower level of absorption of carnitine by the body. However, without providing any sound scientific reasoning, the Office correlates the lower

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<sup>2</sup> In accordance with M.P.E.P. 609(c), the documents cited herein in support of Applicants' remarks are being submitted as evidence directed to an issue raised in the Official Action, and no fee pursuant to 37 C.F.R. 1.97 or 1.98, or citation on a FORM PTO/SB/08 or PTO-1449 is believed to be necessary.

concentration of carnitine (vis-à-vis the other amino acids therein) in the composition of Brantman with a lack of importance. Such logic is flawed. Those of ordinary skill in the art would have appreciated that although carnitine is present in the body in far lower amounts than most, if not all, other amino acids, it is nonetheless *critical* for fatty acid oxidation (and is required to utilize fats as an energy source), and for ammonia detoxification. As such, one of ordinary skill in the art would not have equated the lower concentration of carnitine with a lack of importance, or with the endogenous carnitine level as being sufficient for maximal protein synthesis; to the contrary, they would understand the lower concentration of carnitine in the composition of Brantman to be reflective of the differing biological role of this amino acid vis-à-vis the other amino acids therein, not reflective of its criticality.

Furthermore, Applicants respectfully submit that the instant composition is not obvious over Brantman because the modification to the composition of Brantman proposed by the Office (*i.e.*, omission of carnitine) renders it unsatisfactory for its intended purpose; relevant law holds that if a proposed modification would render a prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Brantman expressly discloses that the intended purpose of the composition is to provide “a dietary supplement which provides the best metabolic milieu to permit and encourage protein synthesis in skeletal muscle and in liver … [and that] the critical feature of this invention is the specific application of certain amino acids (carnitine, glutamine, isoleucine, leucine and valine), which are known to exert net stimulatory effects on protein synthesis in skeletal muscle and liver.” Thus, by omitting carnitine, the composition is rendered unsatisfactory as a dietary supplement

which provides the *best metabolic milieu* to permit and encourage protein synthesis in skeletal muscle and in liver, given that Brantman teach carnitine as being critical for this purpose.

In view of the foregoing, Applicants respectfully submit that one of ordinary skill in the art would not have possessed any motivation to omit carnitine from the composition of Brantman, nor would they have possessed any expectation of success (in view of the criticality of carnitine disclosed by Brantman) that the resulting composition would provide the *best metabolic milieu* for maximal muscle protein synthesis. As such, the presently claimed invention is not rendered obvious.

Withdrawal of the rejection is respectfully requested.

2. On page 5 of the Office Action, Claims 1, 5, 6, 16, 20 and 21 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Verlaan *et al.* (U.S. Patent No. 7,288,570), as evidenced by “Health Publications,” published October, 2002.

In making the rejection, the Office contends that Verlaan *et al.* disclose the Megawhey<sup>TM</sup> product as containing whey, glutamine, isoleucine, leucine, and valine, and that the Megawhey<sup>TM</sup> product stimulates the production of proteins *in vivo*. The Office acknowledges that the Megawhey product contains numerous other components, and thus does not teach the claimed composition.

However, the Office contends that one of ordinary skill in the art at the time of the invention was aware that the “essential ingredients” in Megawhey<sup>TM</sup> are whey protein, glutamine and branched amino acids (*i.e.*, isoleucine, leucine, valine), and that the remaining components, namely lipids, carbohydrates, calcium, potassium, taste enhancers, etc., “are merely extra

additives that contribute additional nutritional value to the composition but which are not critical to stimulating protein production *in vivo*.”

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

To sustain the rejection, the Office appears to take official notice of the fact that those of ordinary skill in the art at the time of the invention were aware that *only* the whey protein, glutamine, isoleucine, leucine and valine components of Megawhey<sup>TM</sup> contributed to stimulating protein production, and that the remaining components are merely nutritional additives that do not affect protein production. On this basis, the Office contends that those of ordinary skill in the art would readily omit the remaining elements from Megawhey<sup>TM</sup> so as to arrive at the claimed composition.

However, Applicants respectfully submit that such a position is founded in impermissible hindsight reconstruction, relying solely upon Applicants' disclosure to bridge the gap between the reference disclosure and the claimed invention. The record to date lacks any evidentiary basis even tending to suggest that those of ordinary skill in the art at the time of the invention would have considered *only* the whey protein, glutamine, isoleucine, leucine and valine components of Megawhey<sup>TM</sup> to contribute to protein production. To maintain a *prima facie* case of obviousness, the Examiner is required to provide supporting documentary evidence to support a conclusion of obviousness. However, official notice may be taken if the facts relied upon in the rejection are “capable of such instant and unquestionable demonstration as to defy dispute.” See *In re Ahert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970). Applicants respectfully disagree that the Office's assertion is capable of instant and unquestionable demonstration as being well known. For example, those of ordinary skill in the art at the

time of the invention would have appreciated that the lipid and carbohydrate components of Megawhey™ also influence net protein synthesis or production; in the “Health Publications” document relied upon by the Office, and in Brantman (see column 2, lines 46-48), it is disclosed that in a carbohydrate depleted state, such as during strenuous or extended periods of exercise, body protein is catabolized as a fuel source, resulting in a loss of body protein. Those of ordinary skill in the art at the time of the invention would readily have appreciated that the carbohydrates and lipids in the composition of Megawhey™ are preferred energy sources which would serve to reduce body protein catabolism for energy, thus enhancing net protein production. Thus, Applicants respectfully submit that the Office’s assertion is not capable of instant and unquestionable demonstration as being well known, and thus the rejection is improper and should be withdrawn.

Further still, because those of ordinary skill in the art would appreciate that the carbohydrates and lipids in the composition of Megawhey™ are preferred energy sources that would serve to reduce body protein catabolism for energy, they would also appreciate that their omission would be detrimental to a composition for maximizing protein synthesis in muscle during strenuous exercise (the purpose of the composition of Brantman).

In view of the foregoing, Applicants respectfully submit that one of ordinary skill in the art would not have possessed any motivation to modify the Megawhey™ composition in the manner asserted in the rejection, nor any expectation of success in doing so, when producing a composition for maximal protein synthesis. As such, the presently claimed invention is not rendered obvious.

Withdrawal of the rejection is respectfully requested.

### Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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